

## Dossier for *Lovaza*

This information is provided in response to your request for information about Lovaza™ (omega-3-acid ethyl esters) capsules.

Lovaza™ was formerly known as Omacor® (Reliant Pharmaceuticals, Inc. Liberty Corner, New Jersey). The name was changed in the United States as of August 2007 at the request of the Food and Drug Administration in response to a limited number of reports of prescribing and dispensing errors resulting from the similarity in the names Omacor® and Amicar® (aminocaproic acid; Xanodyne Pharmaceuticals, Newport, Kentucky). Amicar® is a registered trademark of Xanodyne Pharmaceuticals, Newport, Kentucky.

### SUMMARY

- This dossier is provided per your request.
- Important safety information is found in the attached Prescribing Information.

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Attached is a copy of the requested dossier for your review.

**Some information contained in this response may not be included in the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling.**

**In order for GlaxoSmithKline to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 888-825-5249. Please consult the attached Prescribing Information.**

**This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.**

**This Dossier is provided as a professional service in response to your unsolicited request. Confidential information may be provided within this Dossier. GSK requests that the recipient of this Dossier only share the contents with the Pharmacy & Therapeutics (P&T) Committee members for the purposes of making evidence-based decisions regarding formulary inclusion.**